



## UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/448,378 11/23/99 BRASEL

K 2836-D

HM22/0414

EXAMINER

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ART UNIT	PAPER NUMBER
1644	3

DATE MAILED:

04/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/448,378	Applicant(s) Brasel et al
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

Responsive to communication(s) filed on \_\_\_\_\_

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-19 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

## DETAILED ACTION

This application is a continuation of application 08/725,540.

Claims 1-19 are currently pending in this application.

5                   **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

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### *Election/Restriction*

1.         Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I.         Claims 1 -5, drawn to a method of enhancing an immune response to treat infectious disease, classified in 424, subclasses 85.1 and 204.1.
  - II.         Claims 1, 2, 6, and 7, drawn to a method of enhancing an immune response to treat cancer, classified in Class 424, subclass 277.1.
  - III.         Claims 1 and 18, drawn to a method of inducing tolerance, classified in Class 424, subclass 184.1.
  - IV.         Claims 8-11, drawn to a population of antigen-pulsed dendritic cells, classified in Class 435, subclass 372.
  - V.         Claims 12-14, drawn to method of differentiating hematopoietic cells, classified in Class 435 , subclass 377.
  - VI.         Claim 15, drawn to a method of preparing antigen-specific T cells, classified in Class 435, subclass 372.3.
  - VII.         Claim 16, drawn to a method of enhancing vaccination, classified in Class 424, subclass 184.1.
  - VIII.         Claim 17, drawn to a vaccine adjuvant, classified in Class 424, subclass 278.1.

IX. Claim 19, drawn to cell expansion media, classified in 435, subclass 431.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, antigen-specific T cell can be prepared by culturing T cells with freshly prepared macrophages and antigen.

Inventions VIII and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, the adjuvant can be used to generate antibodies to flt3-L or c-kit.

Inventions I, II, III, V, VI, and VII are unrelated methods. These inventions require different ingredients, process steps and endpoints to accomplish the use of enhancing an immune response, treating an infectious disease, treating cancer, preparing particular cell populations, inducing antigen-specific T cells, enhancing vaccination, and inducing tolerance. Therefore, they are patentably distinct.

Inventions IV, VIII, and IX are different products. Cells, adjuvant, and expansion media are distinct because their structures and functions are different, which require non-coextensive searches. Therefore, they are patentably distinct.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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*Conclusion*

15 6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

20 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calendar) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

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30 F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
April 14, 2000



F. PIERRE VANDERVEGT  
PATENT EXAMINER